Case Management for Patients with Poorly Controlled Diabetes: A Randomized Trial

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PURPOSE: To evaluate the effects of a collaborative case management intervention for patients with poorly controlled type 2 diabetes on glycemic control, intermediate cardiovascular outcomes, satisfaction with care, and resource utilization.

METHODS: We conducted a randomized controlled trial at two Department of Veterans Affairs Medical Centers involving 246 veterans with diabetes and baseline hemoglobin A_{1C} (HbA_{1C}) levels ≥7.5%. Two nurse practitioner case managers worked with patients and their primary care providers, monitoring and coordinating care for the intervention group for 18 months through the use of telephone contacts, collaborative goal setting, and treatment algorithms. Control patients received educational materials and usual care from their primary care providers.

RESULTS: At the conclusion of the study, both case management and control patients remained under poor glycemic control and there was little difference between groups in mean exit HbA_{1C} level (9.3% vs. 9.2%; difference = 0.1%; 95% confidence interval: −0.4% to 0.7%; $P = 0.65$). There was also no evidence that the intervention resulted in improvements in low-density lipoprotein cholesterol level or blood pressure control or greater intensification in medication therapy. However, intervention patients were substantially more satisfied with their diabetes care, with 82% rating their providers as better than average compared with 64% of patients in the control group ($P = 0.04$).

CONCLUSION: An intervention of collaborative case management did not improve key physiologic outcomes for high-risk patients with type 2 diabetes. The type of patients targeted for intervention, organizational factors, and program structure are likely critical determinants of the effectiveness of case management. Health systems must understand the potential limitations before expending substantial resources on case management, as the expected improvements in outcomes and downstream cost savings may not always be realized. **Am J Med. 2004;116:732–739.**

The health and economic consequences associated with diabetes mellitus are well known (1–5). However, despite a growing array of efficacious treatments to prevent some of the most severe diabetes-related complications (6–11), many of the more than 15 million persons with diabetes in the United States continue to have far from optimal glycemic, blood pressure, and lipid control, incurring preventable complications and excessive health care costs (12–18).

One popular strategy for addressing the needs of patients with complex, chronic health conditions is case management (19–22), which is the improved coordination and monitoring of the services required to meet the individual health needs of a specified patient population (20,23–25). Although conceptually appealing (26,27), evidence supporting the effectiveness of this approach remains limited (25,28,29). While most of the published literature supports case management for diabetes, few rigorous clinical trials have been conducted (20,22,30). Additionally, many studies have substantial limitations, such as poor follow-up, and virtually all have been conducted within managed care settings (22).

In an era of increasing resource constraints, it is important to understand when high-cost programs such as case management truly improve health outcomes or decrease costs. We conducted a randomized trial to evaluate the effectiveness of a collaborative case management intervention for patients with type 2 diabetes, focusing on glycemic control but with attention also to blood pressure and lipid control. This intervention was guided by the Chronic Care Model and by interventions that have been reported to be effective within managed care (31,32).

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METHODS

This study was conducted as a prospective, randomized controlled trial at two academically affiliated Department of Veterans Affairs (VA) Medical Centers: a suburban facility that cares for approximately 3000 veterans with diabetes and an inner-city facility that cares for over 4000 veterans with diabetes. Approval was obtained from Institutional Review Boards at the Ann Arbor VA Healthcare System and Wayne State University.

Using automated clinical data from each facility, we identified potential study subjects as those with at least one prescription for an oral hypoglycemic agent, insulin, or blood glucose monitoring supplies filled in the previous 12 months (33,34), whose most recent hemoglobin A_{1C} (HbA_{1C}) level was ≥8.5% (within the last year) and who had a general medicine clinic visit scheduled between May 1999 and January 2000. Patients were recruited by telephone. Ineligible participants were those who were younger than 18 years; were never diagnosed with diabetes; had type 1 diabetes or were diagnosed before the age of 30 years; had no telephone; did not speak English; were not competent for interview; reported primary source of diabetes care outside the VA; were being treated for cancer (other than nonmelanoma skin cancer); had kidney failure, symptomatic heart failure, liver disease, or blindness; spent winter at another residence; or planned to move.

Eligible patients were invited to a baseline examination, at which time a current HbA_{1C} value was obtained. Patients with baseline levels ≥7.5% were invited to enroll in the study and assigned randomly to the intervention or control group. Specifically, we used a conventional stratified (block) randomization allocation design (35), whereby patients were identified in pairs according to site and baseline HbA_{1C} level (moderate control 7.5% to 8.4% vs. poor control ≥8.5%). One member of a matched pair, within one of four possible blocks/cells (site by baseline HbA_{1C} level), was then assigned randomly to the case management group and the other to the control group by the project manager who had no knowledge about the patients other than site and baseline HbA_{1C} level.

Of 691 potentially eligible patients, 246 were enrolled (96 in the moderate control stratum and 150 in the poor control stratum) (Figure). We hypothesized that the intervention would be most effective for those with the poorest glycemic control; therefore, our sampling and allocation strategy was designed to ensure moderate statistical power for a subgroup analysis of patients with baseline HbA_{1C} levels ≥8.5%. Given 150 subjects with poor glycemic control and a baseline HbA_{1C} SD of 1.5%, we anticipated having 80% power ($\alpha = 0.05$ [two-sided test]) to detect a difference in mean HbA_{1C} level of 0.5%. All results are presented using two-tailed testing, although none of our conclusions would change if we used one-tailed testing as specified in our original analysis plan.

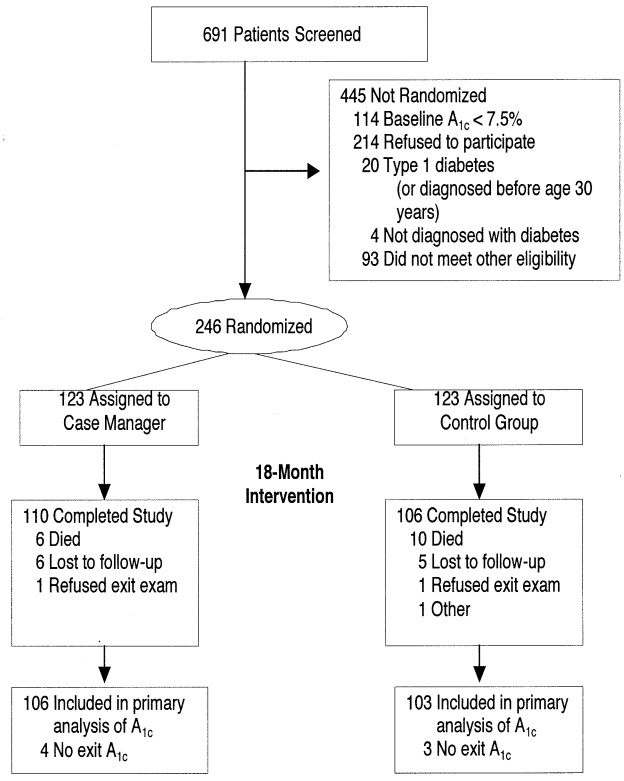

Figure. Participant flow diagram.

Intervention

All study participants were given an A&D Medical semiautomatic blood pressure monitor (Model UA-702H; Milpitas, California), home blood pressure monitoring guidelines, a lay version of the VA Diabetes Clinical Guidelines (36), and a periodic study newsletter. Otherwise, patients assigned randomly to the control group received usual care from their primary care provider while intervention patients were assigned to a case manager. One nurse practitioner case manager at each site, working 20 hours a week, provided care for about 60 patients (120 patients per full-time case manager).

We hypothesized that case managers would facilitate more timely and appropriate changes in medication treatment; prompt detection of potential problems; and better patient self-management. Patient contact occurred primarily by telephone, although face-to-face visits could be arranged. To simulate more realistic circumstances, case managers were allowed to schedule follow-ups according to individual patient needs (e.g., someone newly started on a medication generally requires more contacts than someone on a stable regimen). In general, case managers were directed to encourage patient self-management, including diet and exercise; provide reminders for

recommended screenings/tests; help with appointment scheduling; monitor home glucose and blood pressure levels; and identify and initiate medication and dose changes as needed (22,31,32,37). To facilitate treatment changes, medication treatment algorithms (20) were used, modified to correspond with the National VA Diabetes Clinical Guidelines (36). During a 2-day training session, case managers received instruction on collaborative goal setting, with case examples and role-playing used to familiarize them with the treatment algorithms. Other resources included quarterly patient profiles, as well as training updates and reinforcement at 2 months and then at approximately 6-month intervals thereafter.

We used a case manager/primary provider collaborative approach whereby medication changes required approval by the primary care provider. Providers were notified by internal e-mail that a change was recommended and could opt to have the case manager make the adjustment or to address the issue personally. Primary care providers received a summary of the VA Diabetes Guidelines and an overview of the study, and were invited to a clinical conference conducted by the research team. All providers gave permission for their patients to be included in the study.

Data Collection/Outcome Measurement

Primary data sources included physical examinations and patient surveys at baseline and exit, and the VA medical information system (38). At baseline, a study nurse measured blood pressure with an automated blood pressure machine, conducted a foot examination, and collected a fasting venous blood specimen. Our primary outcome was glycemic control, as measured by HbA_{1C} level, but control of low-density lipoprotein (LDL) cholesterol and blood pressure were also principal outcomes (1,8,39,40). All blood samples were analyzed in the same laboratory, with HbA_{1C} levels measured using a Boronate affinity binding assay (Abbott IMx immunoassay system, reference range 4.4% to 6.3%; Abbott Laboratories, Abbott Park, Illinois). Exit examinations were conducted by the case managers as our major outcomes were objectively measured laboratory tests or, for blood pressure, obtained using an automatic machine with a memory function and printout.

Health status and patient satisfaction were assessed using a self-administered written survey, which included the Short Form Health Survey for Veterans (41) and the Patient Satisfaction Questionnaire—Form II (general satisfaction subscale) (42). At exit, patients rated their providers using a 5-point Likert-like scale, which ranged from "one of the best" to "below average". Information on demographic characteristics, receipt of eye screening, aspirin use, and health care services received outside the VA system were also collected in the survey.

Information on inpatient and outpatient encounters, diagnoses, and pharmacy and laboratory use was obtained from the VA medical information system (38). Comorbid conditions were identified by grouping *International Classification of Diseases, Ninth Revision, Clinical Modification* outpatient and inpatient codes into 11 broad categories (e.g., diseases of the circulatory system) using the Clinical Classifications Software (43).

Finally, semistructured telephone interviews were conducted with 40 intervention patients; 20 from each site. Closed- and open-ended questions were used to elicit their views about the care process and potential barriers in reaching treatment goals. The interviews were conducted by a trained qualitative interviewer and were audiotaped to aid transcription.

Statistical Analysis

Outcome differences between treatment groups were examined using two-sided *t* tests, chi-square analysis, and nonparametric tests, as appropriate. Adjusting for baseline characteristics using multivariable regression did not affect the results substantially. Linear and logistic regression were also used for subgroup analyses to assess whether the degree of benefit varied by site or baseline HbA_{1C} level. These models used the exit value as the dependent variable and included the baseline value, site, intervention status, and interaction terms as independent variables. All analyses were conducted on an intention-to-treat basis using Stata 7.0 (College Station, Texas). The analysis plan was stipulated a priori, and the investigators and statistician were blinded to intervention status. Analysis of the qualitative interviews included the use of frequency counts, content analysis, and case analysis (44).

RESULTS

The baseline attributes of the intervention and control groups were similar (Table 1). Except for having a higher percentage of nonwhite participants, study enrollees were demographically representative of VA ambulatory patients. Patients who refused to participate tended to be older than the study participants (mean age, 66 years) and had higher mean HbA_{1C} values (10.1%). Clinically, study participants had poor glycemic control, low physical and mental health scores, and high comorbidity.

Mean ($\pm$ SD) follow-up was 19 $\pm$ 2 months. Follow-up data were obtained for 216 of the 246 randomized patients (Figure). Excluding 6 case management and 10 control patients who died from nonstudy-related causes, the follow-up rate was approximately 94% for both groups, with complete data obtained for more than 90% of intervention and control patients (some patients refused to have exit laboratory tests performed).

Table 1. Baseline Characteristics of the Patients in the Case Management Intervention and Control Groups

Characteristic	Case Management (n = 123)	Control (n = 123)
	Number (%) or Mean ± SD	
Age (years)	61 ± 10	61 ± 11
Men	121 (98)	117 (95)
Currently married	63 (51)	63 (51)
White	72 (59)	72 (59)
Education >12 years	52 (42)	58 (47)
Have insurance other than VA	72 (59)	75 (61)
Health status		
Rate health as fair or poor	50 (41)	61 (50)
Physical component score (scale, 0 to 100)	36 ± 11	35 ± 11
Mental component score (scale, 0 to 100)	47 ± 12	46 ± 14
Comorbid conditions*	4 ± 2	4 ± 2
Clinical characteristics and resource use		
Time since diagnosis (years)	11 ± 10	11 ± 9
Hemoglobin A_{1C} (%)	9.3 ± 1.5	9.2 ± 1.4
LDL cholesterol (mg/dL)	123 ± 37	123 ± 38
Systolic blood pressure (mm Hg)	145 ± 21	145 ± 20
Diastolic blood pressure (mm Hg)	86 ± 12	86 ± 11
Use insulin	57 (46)	61 (50)
Use statin	35 (28)	29 (24)
Use three or more classes of blood pressure medication	23 (19)	23 (19)
Report taking daily aspirin	77 (63)	68 (55)
Report having dilated eye examination in past 12 months	94 (76)	83 (67)

* Based on the sum of 11 disease categories identified using outpatient diagnoses data: neoplasm, endocrine and metabolic diseases (excluding diabetes), diseases of the blood, mental disorders, diseases of the nervous system, diseases of the circulatory system, diseases of the respiratory system, diseases of the digestive system, diseases of the genitourinary system, diseases of the skin, and diseases of the musculoskeletal system.
LDL = low-density lipoprotein; VA = Veterans Affairs.

Control of Hyperglycemia, Hyperlipidemia, and Hypertension

There was no significant intervention effect on glycemic, lipid, or blood pressure control (Table 2). Mean exit HbA_{1C} levels for both case management and control patients were over 9% and the mean change in levels was not different between groups ($P = 0.61$). LDL cholesterol level and diastolic blood pressure decreased while systolic blood pressure increased slightly, but all changes were similar in the intervention and control groups. Subgroup analysis revealed no significant interaction between baseline HbA_{1C} levels and the intervention ($P = 0.86$), suggesting that those with poorer glycemic control at baseline did not differentially benefit from this intervention. Diastolic blood pressure was the only measure for which a significant site effect and a site/intervention interaction were found; however, adjustment for site did not substantially change the results.

Patient Satisfaction

Despite the lack of improvement in other outcomes, patients in the intervention group were significantly more satisfied with their diabetes care and were also more likely to rate the overall care by their diabetes care providers as better than average (Table 2). We found no association between patient satisfaction, based on their general satisfaction scores, and change in HbA_{1C} level ($P = 0.92$).

Utilization of Health Care Resources

Aside from the proportion of patients who received care outside the VA, there was little difference in resource utilization between study groups (Table 3). Intervention and control patients averaged 0.5 hospitalizations and six primary care outpatient visits during the study period. Case management patients were more likely than controls to have undergone a dilated eye examination in the past 12 months (87% vs. 79%) and were also more likely to have been taking daily aspirin (71% vs. 62%). However, neither of these results reached statistical significance. There was no evidence that the intensity of medication treatment was greater in the intervention group based on medication costs, number of medications, and insulin use and dose. We found no significant differences between groups in the use of statins or number of blood pressure medications at the end of the intervention period, even for those whose baseline LDL cholesterol or

Table 2. Intervention Results for Key Physiologic and Satisfaction Measures

Outcome	Case Management (n = 106)	Control (n = 103)		
	Mean (95% Confidence Interval)		P Value*	Absolute Difference (Case Management-Control) (95% Confidence Interval)
Change in hemoglobin A_{1C} (%)	−0.02 (−0.41 to 0.37)	−0.16 (−0.53 to 0.22)	0.61	0.13 (−0.40 to 0.68)
Exit hemoglobin A_{1C} (%)	9.3 (8.9 to 9.7)	9.2 (8.8 to 9.6)	0.65	0.1 (−0.4 to 0.7)
Change in LDL cholesterol (mg/dL)†	−18 (−26 to −10)	−13 (−21 to −4)	0.37	−5 (−17 to 6)
Exit LDL cholesterol (mg/dL direct measure)‡	106 (100 to 112)	109 (102 to 116)	0.50	−3 (−12 to 6)
Change in systolic blood pressure (mm Hg)	3 (−2 to 7)	1 (−3 to 4)	0.53	2 (−4 to 8)
Exit systolic blood pressure (mm Hg)	146 (142 to 151)	144 (140 to 149)	0.56	2 (−4 to 8)
Change in diastolic blood pressure (mm Hg)§	−3 (−5 to −0.06)	−3 (−6 to −1)	0.61	0.85 (−2 to 4)
Exit diastolic blood pressure (mm Hg)	83 (81 to 86)	83 (81 to 85)	0.70	0.62 (−3 to 4)
General satisfaction score‖¶	14 (13 to 14)	13 (12 to 13)	0.04	0.47 (−0.2 to 1)
Rate diabetes care providers as at least better than average (%)‖	82 (51 to 75)	64 (72 to 89)	0.04	18 (6 to 30)

* Two-sample *t* test.

† n = 90 in case management group and n = 82 in control group due to missing LDL cholesterol values, but similar results were obtained when using non-HDL cholesterol (total cholesterol-HDL cholesterol).

‡ To decrease the amount of missing LDL cholesterol data (due primarily to elevated triglyceride levels), we measured exit LDL cholesterol values directly in addition to obtaining a calculated value. We also compared the non-HDL cholesterol component of cholesterol but the results were unchanged.

§ There was a statistically significant ($P < 0.05$) site effect in the diastolic blood pressure model, although the intervention main effect remained nonsignificant ($P = 0.47$). A site effect was not found for any of the other physiologic outcomes.

‖ Predicted values and *P* values from regression analysis adjusting for site, site/intervention interaction, and general health status at baseline. The general satisfaction model also adjusts for the baseline general satisfaction score.

¶ General satisfaction subscale from Patient Satisfaction Questionnaire-Form II, with a score from 1 (low satisfaction) to 20 (high satisfaction).

HDL = high-density lipoprotein; LDL = low-density lipoprotein.

blood pressure levels suggested that further medication therapy was warranted. At the conclusion of the study, case managers reported having substantial contact with 26% of the case-managed patients, moderate contact with 34%, and minimal or no contact with 40%.

Exit Interviews

Data from the semistructured exit interviews indicated that patients were generally satisfied with the care they received from the VA. Patients expressed particularly high satisfaction with the case management program, with over 90% indicating that they would participate in another case management program and encourage others to participate. The case managers were described as attentive, knowledgeable, and caring. The primary criticism expressed by a few patients was having too few visits with their case manager. Patients also identified the following as barriers to managing their diabetes: financial difficulties, problems with scheduling visits, difficulty with making and maintaining lifestyle changes, and frustration with how diabetes self-management interferes with their daily life.

DISCUSSION

Innovative approaches to improve outcomes and decrease costs for persons with chronic health conditions are an increasingly important part of health care. Accordingly, care models such as case management are being actively promoted (26,27,32,45). However, evidence to support the effectiveness of such strategies has been limited, especially for more ill and socially disadvantaged patients (22). This study examined the implementation and effectiveness of an outpatient-based, collaborative case management intervention for patients with poorly controlled type 2 diabetes and substantial disease burden.

We found that the extra attention and assistance provided by case managers failed to improve glycemic, lipid, or blood pressure control in this group of patients. At the end of the 18-month intervention period, glycemic control remained poor (HbA_{1C} level >9%) in both case management and usual care patients, which suggests that in some settings this form of case management is ineffective. Several patient-related and organizational factors may explain these results.

Although we used an approach that was similar to one of the most successful prior studies (20), the patients and setting in our study differ markedly from those evaluated previously (mainly in managed care) (22). In particular, our study was conducted in a setting where patient comorbidity and illness severity were high, social circumstances and support were often poor, and glycemic control for most patients was quite good. Patients were

Table 3. Resource Use during the 18-Month Intervention Period and Medication Status at Exit

	Case Management (n = 110)	Control (n = 106)	
	Number (%) or Mean ± SD		*P* Value
Hospitalized in VA facility	21 (19)	25 (24)	0.42
VA primary care visits	6 ± 4	6 ± 4	0.39*
Received care outside VA	24 (22)	41 (39)	0.007
Report having dilated eye examination in past 12 months	96 (87)	84 (79)	0.11
Report taking daily aspirin	78 (71)	64 (62)†	0.15
Cost for hypoglycemic, lipid-lowering, and blood pressure medications ($)	1003 ± 722	951 ± 684	0.70*
Lipid medications ($)	223 ± 314	185 ± 267	0.25*
Blood pressure medications ($)	181 ± 211	175 ± 235	0.50*
Oral diabetes medications ($)	319 ± 348	284 ± 327	0.30*
Insulin ($)	91 ± 122	120 ± 317	0.77*
Use insulin at exit	60 (55)	63 (59)	0.47
Units per day of insulin for those on insulin	71 ± 34	69 ± 43	0.77
Use statin at exit	51 (46)	40 (38)	0.20
Among those with baseline LDL cholesterol ≥130 mg/dL‡	22 (54)	178 (46)	0.50
Use three or more classes of blood pressure medication	28 (25)	26 (25)	0.88
Among those with baseline diastolic blood pressure >90 mm Hg or systolic blood pressure >140 mm Hg§	17 (25)	18 (30)	0.60
Amount of case manager contact‖			
None	11 (9)	—	
Minimal	38 (31)	—	
Moderate	42 (34)	—	
Substantial	32 (26)	—	

* Wilcoxon rank sum test.
† Based on n = 104; 2 nonrespondents in the control group.
‡ n = 41 in the case management group and n = 37 in the control group who met LDL cholesterol criteria.
§ n = 67 in the case management group and n = 61 in the control group who met blood pressure criteria.
‖ According to case manager self-report.
LDL = low-density lipoprotein; VA = Veterans Affairs.

intentionally recruited from the roughly 15% of patients at these sites who had persistently poor glycemic control. Poor control in this patient group may be heavily determined by complicating social factors, disease severity, and competing demands, and better coordination and more monitoring may not be sufficient to overcome these barriers.

The problem of competing demands surfaced repeatedly in the semistructured patient interviews. Difficulty in contacting patients for follow-up owing to 'disruptive' living situations was also documented frequently by case managers. At one site, over 70% of attempted telephone contacts (including scheduled "phone visits") were unsuccessful, suggesting that a telephone-based format may not be optimal for certain patient groups. While it is possible that a more intensive case management intervention or use of newer hypoglycemic medications could produce better results, they are unlikely to explain the differences between our results and those found in managed care populations, especially considering that the treatment algorithms and case management approach were similar to those used previously. Moreover, to compensate for the greater disease severity, we kept case managers' patient panels small (120 patients per full-time case manager vs. an estimated 300 patients per full-time case manager identified in one study [20]).

The intervention also did not appear to increase the intensity of medication treatment, which was an important component of the intervention. However, this again does not necessarily explain the difference between this and past studies as other studies have reported improving HbA_{1C} levels without increased medication treatment intensity, presumably through motivating improvements in self-management (20).

Although few primary care providers expressed negative feelings about having their patients in the intervention, case managers reported that some primary care providers were unresponsive to contact attempts, perhaps due to their already overloaded schedules or to unrealized intentions (e.g., the providers indicated that they would

make the recommended change at the patients' next visit). It was probably unrealistic to expect the case managers to work collaboratively with all the primary care providers given that the intervention involved such a small proportion of each provider's panel. In fact, the 120 patients cared for by the case managers were under the care of about 55 primary care providers. In such instances, temporary carve-out programs focusing on specific management issues for selected patients (with case managers given full control) may be more effective than a collaborative model. Alternatively, if working with a smaller number of primary care providers who have multiple case-managed patients, then the collaborative approach may be the preferred choice. Based on our experience and the qualitative analyses, other changes in the case management approach that merit future consideration include more face-to-face contact between case managers and both patients and primary care providers and perhaps requiring a stronger patient commitment to working with the case manager.

Finally, previous studies may have overestimated the benefits of case management. Most studies had weak designs (e.g., uncontrolled pre-post comparisons [46,47]), and many had inadequate follow-up of the patients included at baseline (20,37,47,48). There are only two randomized controlled trials with similar interventions that have shown a positive effect (20,30). In one study the observed improvement was small (30), whereas the second had substantially poorer follow-up of intervention patients compared with controls (20), which can be a major source of bias in randomized trials (49).

In conclusion, prevailing wisdom suggests that added support for patients with chronic conditions and their primary care providers will substantially improve care and, ultimately, patient outcomes. We found, as did previous investigators (20,30), that patients liked the case management intervention and were more satisfied with their overall diabetes care. However, we found no evidence that a collaborative case management intervention improved glycemic, blood pressure, or LDL cholesterol control in this group of type 2 diabetes patients with poor control at baseline and substantial disease severity. How these results were influenced by patient selection, system issues, and the operational design of the intervention deserve further study. Nevertheless, our study demonstrates that case management may not be a sufficient strategy for achieving long-term improvements in outcomes for some high-risk patients or in certain practice settings. Consequently, health systems must recognize the potential limitations of this approach before expending substantial resources, time, and effort on case management programs, as the expected improvements in outcomes and downstream cost-savings may not be realized.

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